

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
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 Salama) Atty. Dkt.: 7014-120
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 Patent No. 7,749,534) Examiner: Susan T. Tran
)
 Filed: April 13, 2006) Group Art Unit: 1615

For: PHARMACEUTICAL COMPOSITION COMPRISING OXOPLATIN, THE
SALTS AND DERIVATIVES THEREOF

REQUEST FOR CERTIFICATE OF CORRECTION

Attention Certificate of Corrections Branch
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

It is certified that an error appears or errors appear in the above-identified patent and
that said Letters Patent is hereby corrected as shown below:

In the issued specification:

On column 2, please correct the paragraph starting on line 45 as follows:

-- Said object according to the invention is accomplished by the present invention by means of a kit comprising cis-diammoniumdichloro-trans-dihydroxoplatinum(IV) (cis-oxoplatinum, oxoplatin), particularly salts thereof, and, physically separated therefrom, a base material of a pharmaceutical agent selected from the group comprising a tablet, a capsule, a coated tablet, a suppository, an ointment, a cream, a solution for infusion and/or injection, and optionally information relating to contacting or combining the contents of the kit, said base materials being selected in such a way that, following contacting or combining the cis-diammoniumdichloro-trans-dihydroxoplatinum(IV) with the base material, the capsule comprises oxoplatin:silicon dioxide:mannitol or magnesium stearate at a ratio of 0.1 to 10 :0.1 to 10 :0.1 to 10; the tablet comprises cis-oxoplatin:lactose:corn starch:poly(O-carboxymethyl)starch sodium salt:calcium hydrogen phosphate.times.2H.sub.2O:cellulose powder:magnesium stearate at a ratio of 10 to 500:20 to 150:1 to 10:1 to 10:1 to 10:0.1 to 7; or the tablet alternatively comprises cis-oxoplatin:silicon dioxide:magnesium stearate at a ratio of 0.1 to 10:0.1 to 10:0.1 to 10; the cream comprises cis-oxoplatin:benzyl alcohol:cetyl stearyl alcohol:Macrogol stearate 1000:isopropyl palmitate:glycerol:70% sorbitol solution water at a ratio of 0.2 to 8:0.1 to 7:1 to 10:0.1 to 7:0.1 to 7:0.2 to 8:0.2 to 8:20 to 60; the ointment comprises cis-oxoplatin:propylene glycol:Macrogol stearate 1000:cetyl stearyl alcohol:VASELINE **retrolatum** **petrolatum** at a ratio of 2 to 20:5 to 40:0.1 to 7:1 to 10:25 to 400; the gel comprises cis-oxoplatin:hydroxyethylcellulose:chlorocresol:sodium hydroxide:sodium hydrogen phosphate dihydrate:water at a ratio of 2 to 20:100 to 600:5

to 40:0.1 to 7:20 to 60:3,000 to 50,000; the suppository comprises cis-oxoplatin:silicon dioxide:hardened fat at a ratio of 0.1 to 10:0.1 to 10:30 to 300; or the suppository alternatively comprises cis-oxoplatin:lactose:corn starch:adipic acid sodium:hydrogen carbonate:stearic acid:magnesium stearate:highly dispersed silicon dioxide:Polysorbate 80 at a ratio of 10 to 100:700 to 4,000:200 to 600:10 to 1000:10 to 1,000:1 to 100:1 to 100:1 to 15:0.1 to 10; or the suppository alternatively comprises cis-oxoplatin:lactose.times.1H.sub.2O:corn starch:adipic acid:sodium hydrogen carbonate:stearic acid:magnesium stearate:silicon dioxide:Polysorbate 80 at a ratio of 10 to 100:1,000 to 5,000:300 to 1,000:100 to 1,000:10 to 1,000:1 to 100:1 to 100:1 to 15:0.1 to 7; or the suppository alternatively comprises cis-oxoplatin:lactose.times.1H.sub.2O:corn starch:adipic acid:sodium hydrogen carbonate:stearic acid:magnesium stearate:silicon dioxide:Polysorbate 80 at a ratio of 10 to 1,000 :1,500 to 5,000:300 to 1,000:10 to 1,000:10 to 1,000:1 to 100:1 to 100:1 to 15:0.1 to 7: the solution for injection or infusion comprises cis-oxoplatin:benzyl alcohol:Polysorbate 80:70% sorbitol solution:water at a ratio of 0.2 to 8 :1 to 10 :0.1 to 7 :100 to 800 :100 to 400; or the solution for injection or infusion alternatively comprises cis-oxoplatin:mannitol:water at a ratio of 0.1 to 7:5 to 40 :1 to 10. --

On column 11, please correct the paragraph starting on line 46 as follows:

-- When using the chemotherapeutical agent in the form of an ointment, it is preferred to use an ointment which, in addition to cis-oxoplatin, includes white VASELINE **retrolatum** **petrolatum**, cetyl stearyl alcohol, Macrogol stearate 1000, and propylene glycol. --

On column 11, please correct the paragraph starting on line 51 as follows:

-- In a preferred embodiment of the invention the ointment includes the individual components cis-oxoplatin:propylene glycol:Macrogol stearate 1000:cetyl stearyl alcohol:white VASELINE ~~retrolatum~~ **petrolatum** at a ratio of 2 to 20:5 to 40:0.1 to 7:1 to 10:25 to 400, preferably at a ratio of 5 to 12:10 to 30:0.2 to 3:2 to 9:50 to 250, and more preferably at a ratio of 6 to 10:15 to 25:0.5 to 1.5:3 to 6:100 to 200, and especially at a ratio of 9.1:22:1:4:155. Accordingly, the ointment according to the invention may comprise e.g. 50 mg of cis-oxoplatin, 120 mg of propylene glycol, 5.5 mg of Macrogol stearate 1000, 22 mg of cetyl stearyl alcohol, and 851.5 mg of white VASELINE petrolatum. --

On column 13, please correct the paragraph starting on line 61 as follows:

-- Thus, the invention relates to a method for the production of a chemotherapeutical agent, i.e. a pharmaceutical agent, in which method cis-diammoniumdichloro-trans-dihydroxoplatinum(IV) (cis-oxoplatin), and particularly the salts thereof, are contacted with a base material of a pharmaceutical agent selected from the group comprising a tablet, a capsule, a coated tablet, a suppository, an ointment, a cream, a solution for infusion and/or injection, said base materials being selected in such a way that, following contacting of cis-diammoniumdichloro-trans-dihydroxoplatinum(IV) with the base material, the capsule comprises oxoplatin:silicon dioxide:mannitol or magnesium stearate at a ratio of 0.1 to 10 :0.1 to 10:0.1 to 10; the tablet comprises cis-oxoplatin:lactose:corn starch:poly(O-carboxymethyl)starch sodium salt:calcium hydrogen phosphate.times.2H.sub.2O:cellulose powder:magnesium stearate at a ratio of 10 to 500:20 to 150:1 to 10:1 to 10:1 to 10:1 to 10:0.1 to 7; or the

tablet alternatively comprises cis-oxoplatin:silicon dioxide:magnesium stearate at a ratio of 0.1 to 10:0.1 to 10:0.1 to 10; the cream comprises cis-oxoplatin:benzyl alcohol:cetyl stearyl alcohol:Macrogol stearate 1000:isopropyl palmitate:glycerol:70% sorbitol solution:water at a ratio of 0.2 to 8:0.1 to 7:1 to 10:0.1 to 7:0.1 to 7:0.2 to 8:0.2 to 8:20 to 60; the ointment comprises cis-oxoplatin:propylene glycol:Macrogol stearate 1000:cetyl stearyl alcohol:VASELINE **retrolatum** **petrolatum** at a ratio of 2 to 20:5 to 40:0.1 to 7:1 to 10:25 to 400; the gel comprises cis-oxoplatin:hydroxyethylcellulose:chloroaerosol:sodium hydroxide:sodium hydrogen phosphate dihydrate:water at a ratio of 2 to 20:100 to 600:5 to 40:0.1 to 7:20 to 60:3,000 to 50,000; the suppository comprises cis-oxoplatin:silicon dioxide:hardened fat at a ratio of 0.1 to 10:0.1 to 10:30 to 300; or the suppository alternatively comprises cis-oxoplatin:lactose:corn starch:adipic acid:sodium hydrogen carbonate:stearic acid:magnesium stearate:highly dispersed silicon dioxide:Polysorbate 80 at a ratio of 10 to 100:700 to 4,000:200 to 600:10 to 1000:10 to 1,000:1 to 100:1 to 100:1 to 15:0.1 to 10; or the suppository alternatively comprises cis-oxoplatin:lactose.times.1H.sub.2O:corn starch:adipic acid:sodium hydrogen carbonate:stearic acid:magnesium stearate:silicon dioxide:Polysorbate 80 at a ratio of 10 to 100:1,000 to 5,000:300 to 1,000:10 to 1,000:10 to 1,000:1 to 100:1 to 100 :1 to 15:0.1 to 7; or the suppository alternatively comprises cis-oxoplatin:lactose.times.1H.sub.2O:corn starch:adipic acid:sodium hydrogen carbonate:stearic acid:magnesium stearate:silicon dioxide:Polysorbate 80 at a ratio of 10 to 1,000 :1,500 to 5,000:300 to 1,000:10 to 1,000:10 to 1,000:1 to 100:1 to 100:1 to 15:0.1 to 7: the solution for injection or infusion comprises cis-oxoplatin:benzyl alcohol:Polysorbate 80:70% sorbitol solution:water at a ratio of 0.2 to 8 :1 to 10 :0.1 to 7

:100 to 800 :100 to 400; or the solution for injection or infusion alternatively comprises cis-oxoplatin:mannitol:water at a ratio of 0.1 to 7:5 to 40 :1 to 10. --

On column 22, please correct the paragraph starting on line 51 as follows:

-- In a first test series, tablets, ointments and infusion solutions were tested on various tumor rats developing both internal and external tumors. The other drugs according to the invention were tested in additional, subsequent test series. Following combining of cis-oxoplatin and base material, the tablet included 50 mg of cis-oxoplatin, 39.5 mg of lactose, 2.5 mg of corn starch, 2.5 mg of poly(O-carboxymethyl)starch sodium salt, 2.5 mg of calcium hydrogen phosphate.times.2H.sub.2O, 2.5 mg of cellulose powder, and 0.5 mg of magnesium stearate. Following contacting cis-oxoplatin with base material, the ointment included 50 mg of cis-oxoplatin, 120 mg of propylene glycol, 5.5 mg of Macrogol stearate 1000, 22 mg of cetyl stearyl alcohol, and 851.5 mg of VASELINE ~~retrolatum~~ petrolatum. In a preparation of 5 mg/ml solution, the infusion solution included 5 mg of cis-oxoplatin, 9 mg of benzyl alcohol, 2 mg of Polysorbate 80, 650 mg of 70% sorbitol solution, and 500 mg of water. --

REMARKS

In the response submitted on March 20, 2009, applicant amended different occurrences of the term “vaseline” to “VASELINE petrolatum.” In some instances, the Office uses “VASELINE retrolatum” instead of “VASELINE petrolatum.” The errors corrected herein occurred on the part of the Office.

Respectfully submitted,

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May 27, 2011